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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,880	04/19/2004	Joel M. Blatt	BAYER 3.0-003 CONT	9880
74144	7590	12/06/2007	EXAMINER	
BAYER LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP 600 South Avenue West Westfield, NJ 07090			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			12/06/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/826,880

Applicant(s)

BLATT ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The amendment submitted 10 September 2007 has been received.
2. Claims 1-50 and 61-67 have been cancelled. Claims 51-60 are pending.
3. All rejections not reiterated herein below are withdrawn in light of the amendment to the claims.

### *Priority*

4. Applicant's argument with respect to the priority is acknowledge. Priority is granted to the earliest filed parent, 08/512,844.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 51-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 is vague with respect to the recitation at part (b). The first reagent is recited as forming a first reaction product when "binding to the sample" and the detectable response is recited as being inversely proportional to the analyte concentration. It is unclear what this reagent is that can bind to the "sample" and

produce a response that is inversely proportional to the analyte. If a reagent binds to a "sample", doesn't it produce a response that is proportional? Responses that are inversely proportional normally involve reagents that compete with the sample analyte for binding to a labeled analog of the analyte.

The recitation of "the reaction zone" in the second "wherein" clause lacks antecedent support.

Claim 56 is vague. Where are these reagents disposed on the porous member? In what zone? What is their function?

### *Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 51-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Fitzpatrick et al (US 5,451,504).

Fitzpatrick discloses a device and method comprising a pathway of three zones, a first mobilization zone (i.e. sample application zone), a second trap zone (i.e. test

zone), and a third detection zone (i.e. reference zone), arranged so that the first and the third zone are spaced apart by the second zone. Labeled receptor specific for the analytes is provided on the first zone, the second zone has immobilized ligand (that binds to the labeled reagent when analyte is not present producing a signal that is inversely proportional to the concentration of analyte), the third zone provides for detection a receptor-analyte complex which positively correlates with the presence of analyte in the sample. See column 2, lines 26-36. Fitzpatrick teaches that any arrangement that provides a series of three or more zones in communication so that liquid will move from the first zone through the second into the third zone may be used. Column 3, lines 27-37. In addition to the basic three zones, the sample pathway may also include an application zone for applying sample, and an absorbent zone which facilitates movement of the sample through the zones as well as a control zone. See column 3, lines 37-49.

With respect to claims 52, 53 and 55, Fitzpatrick teaches that the solid support may be a sheet or film with the zones arrayed sequentially along a sample pathway. Other suitable solid phase supports includes nylon, coated plastic and glass, filters, paper, membranes, etc. See column 2, lines 51-68.

With respect to claim 54, Fitzpatrick discloses the possible detection of more than one analytes and appropriate modifications therein. See column 10, lines 47-51.

With respect to claim 56, Fitzpatrick teaches the use of reagents such as antibodies, antigens, etc. See columns 5-7.

With respect to claim 57, Fitzpatrick discloses an application zone that functions as a filter for removing undesirable particles from a sample. See column 9, lines 30-32.

With respect to claim 58, Fitzpatrick teaches labels selected from colloidal gold, dye polymers, colored latex particles, or enzyme conjugated to receptors such as antibodies or antigens. See column 4, lines 26-34 and column 8, lines 30-37.

With respect to claim 59, Fitzpatrick teaches the first reagent in the trap zone is an immobilized ligand comprising an analog of the analyte. See column 7, line 3 through column 8, line 10.

With respect to claim 60, Fitzpatrick teaches that the second reagent is an immobilized binding partner (i.e. an antibody) that binds to the labeled receptor that is bound to the analyte. Detection of signal provides a positive correlation to the concentration of analyte. See column 8, line 13 through column 9, line 15.

Even though Fitzpatrick does not specifically state that the detectable response in the test zone plus the detectable response in the reference zone equal a total detectable response that is substantially constant for a pre-determined range of analyte concentration, Fitzpatrick anticipates the instant claims because this wherein clause is nothing more than an intended use of the device. In other words, it does not alter the structure of the device which is taught in its entirety by Fitzpatrick. A recitation of the

intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### *Response to Arguments*

9. Applicant's arguments filed 10 September 2007 have been fully considered but they are not persuasive.

Applicant argues that neither Fitzpatrick nor Robinson disclose the presently claimed feature set for the in amended claim 51. This argument is not persuasive. Amended claim 51 is actually anticipated by Fitzpatrick because all the structures recited are taught by Fitzpatrick. Even though Fitzpatrick does not call his detection zone a "reference zone", this zone carries the same reagents and has the same function as the detection zone taught by Fitzpatrick, therefore, they are seen to be the same. The fact that Applicant calls it a "reference zone" does not alter its structures or function.

Fitzpatrick also teaches a trap zone that binds uncomplexed or excess labeled receptors producing a signal that is clearly inversely proportional to the analyte concentration.

*Conclusion*

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,308,775 Donovan et al

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bao-Thuy L. Nguyen  
Primary Examiner

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